

Message

From: Vandenberg, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCAE2B98A04540FB8D099F9D4DEAD690-VANDENBERG, JOHN]
Sent: 11/5/2019 9:59:14 PM
To: Walsh, Patrick [patrick-walsh@denka-pe.com]; Robinan Gentry [rgentry@ramboll.com]
CC: Thayer, Kris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ce4ae3f107749c6815f243260df98c3-Thayer, Kri]; Cascio, Wayne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1bd931ca2f84ea8ac2f4c44538f3589-Cascio, Wayne]; Jones, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samantha]; Lavoie, Emma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86ac7844f12646c095e4e9093a941623-Lavoie, Emma]; Schlosser, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=121cf759d94e4f08afde0ceb646e711b-Schlosser, Paul]; Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Kirby, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbb65672f6f34545be460a66ff6fa969-Kirby, Kevin]; Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]
Subject: RE: Chloroprene PBPK: Peer review charge questions

Hi Patrick,

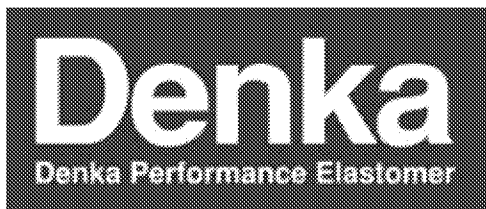
We can send the final charge questions one more time to you to share as you wish with Ramboll before sending to peer reviewers. Our concern is that this level of unprecedented back and forth can potentially undermine the credibility of the peer review and extend the timeline. And for your information, our QA evaluation thus far has revealed important limitations both in the model and in the model documentation. We have been communicating our concerns to Ramboll, providing an opportunity for them to complete and strengthen their package before peer review.

Best regards,
John

From: Walsh, Patrick <patrick-walsh@denka-pe.com>
Sent: Tuesday, November 05, 2019 2:39 PM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Robinan Gentry <rgentry@ramboll.com>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>
Subject: RE: Chloroprene PBPK: Peer review charge questions

Hi John,

I don't mean to be a pain about this, and maybe I read it wrong, but I don't think you answered my question. It makes sense that revisions to the charge questions will wait until Paul has completed his QA review, but will Ramboll get to review and comment on the revised charge questions before they are sent to the peer reviewers?



Patrick A. Walsh, CIH | SHE Manager
Denka Performance Elastomer LLC
560 Highway 44 | LaPlace, LA 70068
Office: 985-536-7573 | Cell: 251-321-5989
patrick-walsh@denka-pe.com

From: Vandenberg, John <Vandenberg.John@epa.gov>
Sent: Tuesday, November 5, 2019 11:47 AM
To: Walsh, Patrick <patrick-walsh@denka-pe.com>; Robinan Gentry <rgentry@ramboll.com>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>
Subject: RE: Chloroprene PBPK: Peer review charge questions

Hi Patrick,

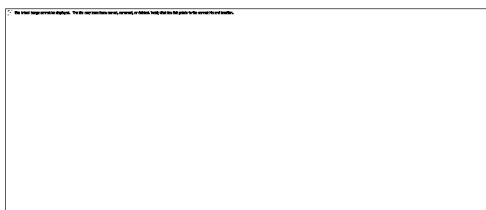
No problem at all - we are working on this and as you know there are technical communications going back and forth between our PBPK folks and Ramboll that may inform the charge questions and materials provided to the peer reviewers. We can't finalize the charge questions until the QA efforts are complete and the technical materials are ready for review.

John

From: Walsh, Patrick <patrick-walsh@denka-pe.com>
Sent: Tuesday, November 05, 2019 12:12 PM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Robinan Gentry <rgentry@ramboll.com>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>
Subject: RE: Chloroprene PBPK: Peer review charge questions

Hi John,

Sorry, didn't mean to sound like I was rushing you. I appreciate the mini-update. Is Ramboll going to get a chance to review and comment on the updated charge as requested?



Patrick A. Walsh, CIH | SHE Manager
Denka Performance Elastomer LLC
560 Highway 44 | LaPlace, LA 70068
Office: 985-536-7573 | Cell: 251-321-5989
patrick-walsh@denka-pe.com

From: Vandenberg, John <Vandenberg.John@epa.gov>
Sent: Tuesday, November 5, 2019 10:53 AM
To: Walsh, Patrick <patrick-walsh@denka-pe.com>; Robinan Gentry <rgentry@ramboll.com>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>;

Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>

Subject: RE: Chloroprene PBPK: Peer review charge questions

Hi Patrick,

We're still working through QA of the Ramboll materials, making peer review contract arrangements, and revising the charge for the panel.

Moving as fast as we can!

John

From: Walsh, Patrick <patrick-walsh@denka-pe.com>

Sent: Tuesday, November 05, 2019 11:33 AM

To: Vandenberg, John <Vandenberg.John@epa.gov>; Robinan Gentry <rgentry@ramboll.com>

Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>

Subject: RE: Chloroprene PBPK: Peer review charge questions

Hi John,

Happy Tuesday. Just checking in to see how things were moving along with the charge questions and if you or your staff needed any clarifications. Thanks!



Patrick A. Walsh, CIH | SHE Manager
Denka Performance Elastomer LLC
560 Highway 44 | LaPlace, LA 70068
Office: 985-536-7573 | Cell: 251-321-5989
patrick-walsh@denka-pe.com

From: Vandenberg, John <Vandenberg.John@epa.gov>

Sent: Monday, October 21, 2019 2:23 PM

To: Robinan Gentry <rgentry@ramboll.com>

Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>; Walsh, Patrick <patrick-walsh@denka-pe.com>

Subject: RE: Chloroprene PBPK: Peer review charge questions

Robinan,

We received the email with your comments on the draft Peer Review charge questions on Friday, Oct 18. We'll evaluate your comments and let you know of next steps, and I will contact you if we have any questions.

Thank you,

John

From: Robinan Gentry <rgentry@ramboll.com>

Sent: Friday, October 18, 2019 2:55 PM

To: Vandenberg, John <Vandenberg.John@epa.gov>

Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>; Walsh, Patrick <patrick-walsh@denka-pe.com>

Subject: RE: Chloroprene PBPK: Peer review charge questions

John,

Attached please find a document summarizing Ramboll's comments on the draft charge peer review of the Ramboll (2019) Chloroprene PBPK model. While we greatly appreciate USEPA's efforts to work with us to ensure the development of a PBPK model that is scientifically sound, we have significant concerns regarding the current draft of the charge for the external peer review of our model. Our concerns include:

1. Content and format of the draft charge that is inconsistent with the USEPA Peer Review Handbook (2015) and similar charges for USEPA peer reviews;
2. Presentation of USEPA opinions as fact in the Background to the draft charge questions that may introduce bias and in some cases are incorrect;
3. Inclusion of the USEPA (2019) 1-CEO Clearance Analysis as a component of the charge to the peer review in the absence of clearly providing the relevance of this analysis to the evaluation of the Ramboll (2019) PBPK model. Further, in our review of the USEPA (2019) Analysis, we identified discrepancies that significantly impact any results or conclusions that may be drawn based on this analysis.

Because of these concerns and the identification of potential errors, we are requesting that USEPA revise the draft Charge for the peer review of the Ramboll (2019) Chloroprene PBPK model, as well as the USEPA (2019) 1-CEO Clearance Analysis. Further, we would also request time to review the revised charge and any revisions to the USEPA (2019) 1-CEO Clearance Analysis and provide recommendations as appropriate prior to USEPA finalizing these documents and providing them to the peer reviewers.

After you have had time to review our comments, if you have any questions, please feel free to contact me.

Thanks,
Robinan

Robinan Gentry

Principal

D +1 (318) 3982083

M +1(318) 5472429

rgentry@ramboll.com

From: Walsh, Patrick <patrick-walsh@denka-pe.com>

Sent: Thursday, October 17, 2019 11:10 AM

To: Vandenberg, John <Vandenberg.John@epa.gov>

Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <schlosser.paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>; Robinan Gentry <rgentry@ramboll.com>

Subject: RE: Chloroprene PBPK: Peer review charge questions

Hello John,

A quick update:

Ramboll has been hard at work on their detailed response to the peer review charge questions. They expect to be complete well within our revised timeframe. Robinan Gentry of Ramboll will send the comments to this group tomorrow before close of business. Thanks for your patience and for including us in this process.

Patrick A. Walsh, CIH | SHE Manager
Denka Performance Elastomer LLC
560 Highway 44 | LaPlace, LA 70068
Office: 985-536-7573 | Cell: 251-321-5989
patrick-walsh@denka-pe.com

From: Vandenberg, John <Vandenberg.John@epa.gov>
Sent: Thursday, October 10, 2019 8:02 AM
To: Walsh, Patrick <patrick-walsh@denka-pe.com>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>
Subject: RE: Chloroprene PBPK: Peer review charge questions

Hi Patrick,

Thank you for letting me know the status of your review - we had thought from your email last Thursday that a week was adequate time. We don't want to have any delays moving forward with the peer review but it seems you have comments that we would like to consider, so we agree to wait another 9 days. Please let us know if you have any comments as they are available.

In addition, it seems some changes are being made to your report to make corrections and add clarifications as indicated in recent emails between EPA and your contractors. Any discrepancies need to be resolved before sending the materials for peer review so please use this time to recheck and update your report to avoid delays.

Thank you,
John

From: Walsh, Patrick <patrick-walsh@denka-pe.com>
Sent: Wednesday, October 09, 2019 4:54 PM
To: Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; Dunlap, David <dunlap.david@epa.gov>
Subject: RE: Chloroprene PBPK: Peer review charge questions

Hi John,

We need more time for us to provide recommendations regarding the chloroprene PBPK model peer review charge questions you sent me last Wednesday. There are 3 reasons for this request:

1. One of our experts, Mel Andersen, had a previous engagement that could not be moved and he has not been able to contribute to the effort. That commitment ends today and he is travelling tomorrow.

2. We need time to review the new clearance report because of the way it is being used to frame charge questions.
3. We have grave concerns that the manner in which certain information is presented will bias the reviewers inappropriately, and we need more time to ensure that we assemble a cogent and helpful set of recommendations to ensure the most objective review possible.

To that end, I'm requesting a little more time—can we submit our recommendations to you by close of business Friday, 10/18?

Thanks

Patrick A. Walsh, CIH | SHE Manager
Denka Performance Elastomer LLC
560 Highway 44 | LaPlace, LA 70068
Office: 985-536-7573 | Cell: 251-321-5989
patrick-walsh@denka-pe.com

From: Vandenberg, John <Vandenberg.John@epa.gov>
Sent: Wednesday, October 2, 2019 3:46 PM
To: Walsh, Patrick <patrick-walsh@denka-pe.com>
Cc: Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Schlosser, Paul <Schlosser.Paul@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>
Subject: Chloroprene PBPK: Peer review charge questions
Importance: High

Patrick,

We've been diligently evaluating the Ramboll report and conducting analyses related to physiologically-based pharmacokinetic parameters and modeling of chloroprene (references below).

We are moving forward to arrange through a contractor an independent letter peer review by appropriate experts.

In addition to the Ramboll report, we are providing an EPA analysis that we wish to have peer reviewed.

Per our discussion early this summer, we are providing for your information the attached draft Charge questions that will be addressed by the peer reviewers, plus an EPA analysis that we have developed.

Please let us know within a week (by next Wednesday) if you have any major comments on the Charge questions. We are not seeking any comments on the EPA analysis.

Thank you,

John

John Vandenberg, PhD
Director, Health and Environmental Effects Assessment Division
Center for Public Health and Environmental Assessment/ORD
U.S. Environmental Protection Agency/B243-01
Research Triangle Park, NC 27711
(919) 541-4527

References:

- Ramboll. (2019). Incorporation of in vitro metabolism data in a physiologically based pharmacokinetic (PBPK) model for chloroprene.
- U.S. EPA. (2019). In Vitro to In Vivo Extrapolation (IVIVE) of Metabolism and Non-Enzymatic Conjugation of (1-chloroethenyl)oxirane (1-CEO) and Estimation of Total 1-CEO Clearance in the Liver and Lung of Mice, Rats, and Humans.